### REMARKS/ARGUMENTS

Claims 26, 28-32, 35-43, 45-49, 51, 52, 54, 55, 57, 59, 61 and 62 are pending in this application. All of the pending claims are presently rejected.

In this Response, claims 26, 29, 30, 40, 42, 43, 45, 48, 49, 52, 54, 55, 57 and 61 are amended. Furthermore, claims 59 and 62 are canceled without prejudice or disclaimer. The amendments are supported by the application as originally filed and thus there is no issue of new matter. Entry of the amendments into the file of the present application is respectfully requested. Upon such entry, claims 26, 28-32, 35-43, 45-49, 51, 52, 54, 55, 57 and 61 will be pending in this application.

The Examiner is requested to reconsider and withdraw all of the objections and rejections set forth in the Office Action and to issue a Notice of Allowance regarding the subject application.

### Claim Objections

As indicated on p. 3, the Objection to claims 26, 28-32, 35-43, 45-49, 51, 57 and 59 for containing non-elected subject matter is maintained for the reasons of record. According to the paragraph bridging pp. 2-3 of the Action, "[t]he election of Group I directed to compounds of formula (I) was without traverse and therefore, the claims must be amended to compounds of formula (I), a process for preparing such compounds and methods of treatment using these compounds".

Applicant has, therefore, in response amended claims 26 and 43 such that all of the presently pending claims are directed either to compounds of formula (I), a process for preparing such compounds or to a method of treatment using the subject compounds. The Examiner is thus requested to reconsider and withdraw the objection to applicant's claims.

Applicant specifically reserves his right to pursue patent protection for claims <u>not</u> limited to compositions and methods using formula (I) in one or more subsequently filed divisional applications.

### **Enablement Rejections**

As further indicated on p. 3 of the Office Action, the rejection of claims 26, 28-32, 35-43, 45-49, 51, 52, 54, 55, 57, 59, 61 and 62 under 35 U.S.C. §112, first paragraph, is maintained for the reasons of record.

In regard, first, to the 'enablement' rejection based on the use of the term "deivative(s)" in the claims, applicant submits that as indicated at p. 3, lines 6-7 of the previous Office Action dated November 3, 2008, the Examiner has apparently characterized the term "derivative" as referring to a hydrate, solvate or prodrug form, i.e., of the subject chelidonine. Applicant respectfully submits, however, that this is believed to be a mischaracterization of the term's usage in the present application. That is, a 'typical' definition of the term in the chemical art is as, "a compound that is formed from a similar compound or a compound that can be imagined to arise from another compound if one atom is replaced with another atom or group of atoms" (see the attached printout from the Wikipedia online website. When one interprets the claims taking the above definition into account, applicant respectfully submits that the subject claims are all believed to meet the requirements for enablement under 35 U.S.C. §112, first paragraph.

Notwithstanding the above explanation, however, in order to clarify the record and to prevent any misunderstanding or mischaracterization regarding the 'proper' meaning of the term "derivative", applicant has amended claims 26, 29, 40, 42, 43, 45, , 48, 49, 52, 54, 55 and 61 to change "chelidonine derivative" to "chelidonine reaction product" in order to clarify the language of the claims. Support for this amendment is found throughout the specification of the application as originally filed and thus no issue of new matter is raised. See, for example, p. 2, lines 13-15 which speaks of the, "preparation of a reaction product of alkaloids, particularly of chelidonine . . . . with suitable alkylating agents . . . . ". The above-cited language is cited as providing one supporting example of the new terminology added to the claims which, as noted above, is supported by numerous additional examples throughout the as-filed specification.

Still further, at p. 2 the Office Action states that in regard to the enablement rejection for methods of treatment, the Examiner does not agree with the applicant's arguments that efficacy of U-KRS in various medical applications is disclosed in examples 4-23. The rejection is respectfully traversed.

In response, applicant submits that Examples 4-23 each clearly contain "Results" and it is maintained that the results so provided in the subject Examples sufficiently demonstrate support for the efficacy of U-KRS in (at least) the treatment of cancer, osteoporosis and radiation damage. More specifically, there are provided a number of examples wherein U-KRS was tested and found to be efficient in various cell lines (see, e.g., Examples 5 and 7-13). Specific proof of efficacy of U-KRS in the treatment of osteoporosis and radiation damage is given in Example 19 and in Examples 22 and 23, respectively.

For each of the biological tests described in the subject Examples, the relevant materials and method steps are disclosed, as are the beneficial results achieved with the use of the claimed compositions and methods. One of ordinary skill in the relevant art, relying on their general common knowledge would, in applicant's view, be readily able to reproduce the Examples based on the information provided in the application and would, therefore, arrive inevitably at the indicated results.

In light of the matters discussed above, and to advance the prosecution of this application, applicant has amended claims 57 and 61 such that as amended the subject claims refer only to cancer, osteoporosis and radiation damage. Further, claims 59 and 62 have been cancelled from the application without prejudice or disclaimer. As amended, therefore, the claims of the application are all submitted as meeting the enablement requirement of 35 U.S.C. §112. The Examiner is thus respectfully requested to reconsider and withdraw the rejection of applicant's claims based on §112, first paragraph.

### Rejections Under 35 U.S.C. §102(b)

Claims 52, 54, 55, 57, 59, 61 and 62 are rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Zbierska, et al., *Herba Polonica*, Vol. 25, pp. 311-316 (1979). Claims 59 and 62 are canceled in this response without prejudice or disclaimer. Thus the rejection will be treated as affecting the remaining claims, i.e., nos. 52, 54, 55, 57 and 61. The rejection is respectfully traversed.

Applicant's initial arguments with regard to the subject rejection are set forth on p. 11 of the previous Amendment dated March 3, 2009. Those remarks are specifically incorporated by reference into the present Amendment by reference thereto. The Examiner, however, in the "Response to Arguments" as set forth on p. 2 of the Office Action, states that, "[t]he Examiner does not agree with applicant's arguments that the cited reference does not anticipate the instant claims when the variable R1 represents a methyl group in the instant claims of formula (I)".

In response to this ground of rejection claim 52 is amended herein to delete the recitation of R1 as a methyl group. The amendment, however, is without prejudice or disclaimer to applicant's right to pursue patent protection in a subsequently filed divisional application for a chelidonine reaction product according to claim 52 wherein R1 is a methyl residue.

As amended, therefore, claim 52 and claims 54, 55, 57 and 61 are believed to be distinguishable over the Zbierska, et al. reference for the reasons given at p. 11 of applicant's prior Amendment (as well as at pp. 12-13). The Examiner is, therefore, respectfully requested to reconsider and withdraw the subject rejection.

### Summary

The claim amendments and arguments presented herein are believed to overcome all of the objections to the claims and the claim rejections set forth in the Office Action. The Examiner is, therefore, respectfully requested to withdraw the objections and rejections and to issue a Notice of Allowance for all of the claims of the present application.

THIS CORRESPONDENCE IS BEING SUBMITTED ELECTRONICALLY THROUGH THE PATENT AND TRADEMARK OFFICE EFS FILING SYSTEM ON July 1, 2009.

Respectfully submitted,

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# Derivative (chemistry)

From Wikipedia, the free encyclopedia

if one atom is replaced with another atom or group of atoms.[1] The latter definition is common in organic chemistry. In biochemistry, the word is used In chemistry, a derivative is a compound that is formed from a similar compound or a compound that can be imagined to arise from another compound about compounds that at least theoretically can be formed from the precursor compound. [2]

spectroscopic analysis, such methods were widely used. simple way of verifying the identity of the original compound, assuming that a table of derivative MP values is available. [3] Prior to the advent of compounds. A crystalline derivative may be prepared, such as a semicarbazone or 2,4-dinitrophenylhydrazone (derived from aldehydes/ketones), as a Chemical derivatives may be used to facilitate analysis. For example, melting point (MP) analysis can assist in identification of many organic

### See also

Derivatization

## References

- 1. ^ "Definition of Derivative". Chemicool. 2007-09-18. http://www.chemicool.com/definition/derivative.html. Retrieved on 2007-09-18
- Oxford Dictionary of Biochemistry and Molecular Biology. Oxford University Press. ISBN 0-19-850673-2.
- ^ Williamson, Kenneth L. (1999). Macroscale and Microscale Organic Experiments, 3rd ed. Boston: Houghton-Mifflin. pp. 426-7. ISBN 0-395-90220-7.

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